

Notice of Allowability

Application No.

09/622,206

Examiner

James L. Grun

Applicant(s)

HISADA ET AL.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 02 May 2006.
2. ☒ The allowed claim(s) is/are 24-27, renumbered as claims 1-4, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

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| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>08182006</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>05/02/2006</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02 May 2006 has been entered and considered.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in telephone interviews with Mr. Xavier Pillai, on 13 March 2006 and 18 August 2006.

The application has been amended as follows:

IN THE CLAIMS:

Claims 1-23 were cancelled without prejudice or disclaimer thereto.

The following new claims were added:

-- 24. A method for quantitatively detecting an antigen in an analytical sample, said analytical sample suspected of containing an amount of antigen, which comprises:

a) providing a plurality of identical modified recombinant Fab' antibodies having a uniform isoelectric point, each said modified antibody being specific for the antigen and capable of forming an immune complex with any of the antigen in the analytical sample, each said modified Fab' antibody being recombinantly modified from a first antigen specific antibody in having:

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- i) at least one additional charged amino acid residue adjoined to a L-chain C-terminus;
 - ii) a site specific mutation in encoding nucleic acid altering at least one Fd-chain CH1 region amide side chain-containing amino acid residue in said first antibody to a non-amide side chain-containing amino acid residue, except cysteine, in said modified antibody; and
 - iii) a single cysteine residue, which is not involved in binding of the Fd-chain to the L-chain, in an amino acid sequence adjoining the Fd-chain CH1 region C-terminus in the modified Fab' antibody; and,
- each said modified Fab' antibody having a fluorescent dye label bound to the single non-L-chain binding cysteine residue;
- b) contacting the plurality of modified Fab' antibodies having a uniform isoelectric point with the analytical sample in a mixture under conditions sufficient for formation of said immune complexes;
 - c) separating any formed immune complexes from unbound antibodies and antigen by performing electrophoresis of the mixture in a carrier;
 - d) irradiating the electrophoresed mixture in the carrier with an excitation light which excites the fluorescent dye label;
 - e) detecting a level of fluorescence of the separated and irradiated immune complexes or the separated and irradiated unbound antibodies; and
 - f) correlating the detected level of fluorescence with the amount of antigen in the analytical sample.

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25. The method of claim 24 wherein correlating the detected level of fluorescence involves comparing the detected level of fluorescence with a standard curve relating fluorescence intensity with amount of antigen.

26. The method of claim 24 wherein the electrophoresis is performed by isoelectric focusing.

27. The method of claim 24 wherein the electrophoresis is performed by capillary electrophoresis.

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The following is an examiner's statement of reasons for allowance: the prior art of record does not teach or suggest the use of the modified antibody fragments having a uniform isoelectric point as instantly claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
August 18, 2006



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641